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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,767	04/13/2004	Hisataka Fujimaki	K2020.0010/P010	2984
24998 7590 11/06/2007 DICKSTEIN SHAPIRO LLP 1825 EYE STREET NW Washington, DC 20006-5403			EXAMINER BERMAN, JACK I	
			ART UNIT 2881	PAPER NUMBER
			MAIL DATE 11/06/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/822,767

Applicant(s)

FUJIMAKI ET AL.

Examiner

Jack I. Berman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2007 and 22 October 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10, 12, 17, 23, and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al. in view of Yasushi et al. (JP 2001-212253, cited by applicant in the Information Disclosure Statements filed on February 3, 2005 and April 8, 2005). As was explained in the first Office action given for this application, the Chu et al. review article teaches that particle beam irradiation equipment comprising charged particle beam generation equipment and a charged particle beam irradiation nozzle for irradiating a charged particle beam extracted from the charged particle beam generation equipment to an irradiation target, wherein said charged particle beam irradiation nozzle comprises a first scatterer device including a first scatterer through which said charged particle beam passes and a second scatterer device through which the charged particle beam passes after having passed said first scatterer, is known in the

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art. Furthermore, in the paragraph beginning in the right-hand column on page 2082, Chu et al.

teaches:

Scattering characteristics of a given scatterer depend on the incident particle species (charge Z and atomic mass M) and the beam energy. Therefore a double-scattering system developed for a certain beam must be modified if any of these beam parameters are changed. Providing a different occluder system for each particle species and energy used is costly, and changing the systems each time the beam is changed is not practical in clinical operations. *One way to resolve this problem is to vary the locations of the occluder assembly and the second scatterer. When the energy of the beam is modulated by an absorber, and consequently the values of the beam widths are made larger, the occluder assembly may be moved upstream nearer to the first scatterer* [Emphasis supplied] so that the projected radii at the isocenter are proportionally increased. This process compensates the parameters in such a way that the resulting dose distribution again exhibits an acceptable deviation from the average.

This clearly teaches a person having ordinary skill in the art to position a second scatterer in the passage region at a first position in the direction of travel of a charged particle beam when the second scatterer is being configured to provide a smaller scattering strength of the charged particle beam in a direction perpendicular to the direction of travel of the charged particle beam than when the second scatterer is positioned in the passage region at a second position upstream of the first direction in the direction of travel of the charged particle beam. While Chu et al. does not teach how the position of the second scatterer could be varied, Yasushi et al. teaches, at paragraphs [0136]-[0139] of the translation provided by the applicant, that the position of a scatterer can be varied by providing a plurality of scatterers, each of which may comprise a table on which a plurality of different scattering films are mounted, at different locations and to choose which scatterer to use based upon the degree of scattering desired with the position of the chosen scatterer being further upstream of the direction of travel of the charged particle beam when more scattering is required. It would have been obvious to a person having ordinary skill in the art to use Yasushi et al.'s system of plural alternatively selected scatterers at different

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positions along the direction of travel of the charged particle beam to effect the desired function of changing the position of the second scatterer taught by Chu et al. As Yasushi et al. indicates at paragraph [0136], the equipment would have to have a control system (control computer 8) to control the equipment, including the selection of the appropriate second scatterer and it would have been obvious to a person having ordinary skill in the art to base this selection on the treatment plan information, including irradiation field information and energy information of an ion beam, because both Chu et al. and Yasushi et al. teach that the selection of the second scatterer and the energy of the ion beam affect the irradiation of the diseased part of the patient and this irradiation must be carefully matched to the desired treatment plan in order to effectively irradiate only the diseased part of the patient without damaging nearby healthy organs in the patient. It would have been obvious to a person having ordinary skill in the art to use the equipment for its intended function by selecting the selected second scatterer at the selected position and emitting the charged particle beam to pass through the first scatterer and the selected second scatterer. The amendment filed on September 21, 2007 adds to these claims the limitation:

“said plurality of second scatterers of the second scatterer device each being configured to have higher scatter strength in the central side than in the radially outer peripheral side to provide a beam irradiation of a double scattering method in combination with said first scatterer of the first scatterer device”.

This new limitation does not distinguish the claimed invention over the prior art because Chu et al. teaches at the paragraph bridging the left and right columns on page 2083 that the portion of a second scatterer nearer to its center should have a higher scatter strength than a portion farther out from the center, i.e. the “radially outer peripheral side”, in order to compensate for the Gaussian-like beam spot formed as the charged particle beam passes through the first scatterer. It

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would have been obvious to a person having ordinary skill in the art to incorporate this teaching into the Chu et al./Yasushi et al. apparatus discussed above in order to achieve the more uniform irradiation discussed by Chu et al.

Claims 11, 15, 16, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al. and Yasushi et al as applied to claims 1-10, 12, 17, 23, and 26-29 above, and further in view of either Moyers et al. or Hernandez et al. As was explained in previous Office actions, while Yasushi et al. teaches that each of the scatterers may comprise a table on which a plurality of different scattering films are mounted, Yasushi et al. does not teach explicitly how to position the selected scattering film in the path of the charged particle beam. Moyers et al. teaches that moving a selected second scattering film into position can be accomplished by rotating the table on which the plurality of films are mounted so that the table moves in a direction perpendicular to the direction of travel of the charged particles until the selected film is in the appropriate position in the same way as that illustrated in Figure 3 of the instant application. Hernandez et al. teaches that moving a selected scattering film into position can be accomplished by linearly translating the table on which the plurality of films are mounted so that the table moves in a direction perpendicular to the direction of travel of the charged particles until the selected film is in the appropriate position in the same way as that illustrated in Figure 4 of the instant application. It would have been obvious to a person having ordinary skill in the art to use either the Moyers et al. translation apparatus or the Hernandez et al. translation apparatus to provide the required means to move the selected one of the plurality of different scattering films on any one of Yasushi et al.'s scatterers into the appropriate position when that scatterer is moved into the operative position to fulfill the second scatterer function at varied locations taught by Chu et al.

Claims 13, 14, 18-20, 24, 25, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al. and Yasushi et al as applied to claims 1-10, 12, 17, 23, and 26-29 above, and further in view of Huntziger. In the embodiment of the invention illustrated in Figure 11, Huntziger teaches that the position of a scatterer along the direction of travel of a beam of charged particles can be changed by moving the scatterer along this direction of travel. The use of Huntziger's means for moving either the first scatterer or one or more of the second scatterers along the direction of travel of a beam of charged particles instead of or in addition to Yasushi et al.'s means for providing alternatively selectable scatterers at different positions along this direction of travel would have been an obvious substitution of equivalents or an obvious duplication of parts to provide finer control of the resulting beam profile.

Applicant's arguments filed September 21, 2007 have been fully considered but they are not persuasive. Applicant's argument that Chu et al. uses an occluding post or an occluding post and ring is irrelevant because nothing in the claims of the instant application exclude the use of such occluders. Applicant's argument that Chu et al. does not teach to change the thickness of the second scatterer is unpersuasive because, as is explained above and in previous Office actions, Yasushi et al. teaches to place a plurality of scatterers at different positions along the beam axis with each scatterer comprising a plurality of films having different thicknesses from each other so that both the position of a scatterer and its position can be changed to give a greater control of the beam profile and area and it would have been obvious to a person having ordinary skill in the art to use the Yasushi et al. apparatus as the nominally recited movable second scatterer in the apparatus described by Chu et al. Applicant's argument that Yasushi et al. is not directed to a double scattering irradiation system is unpersuasive because the rejection was not based on Yasushi et al. by itself.

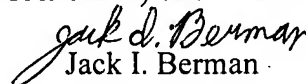
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It is noted that Moyers et al., previously cited, also teaches to make the central part of a second scatterer with a higher scattering strength than that of a peripheral portion by making the scatterer thicker at the central portion.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jack I. Berman whose telephone number is (571) 272-2468. The examiner can normally be reached on Monday-Thursday (8:30-7:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert H. Kim can be reached on (571) 272-2293. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Jack I. Berman
Primary Examiner
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jb
11/1/07